



DOCKET NO: B0877.70025US00


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jill A. O'Loughlin, et al.
Serial No: 10/731,877
Confirmation No: Not Yet Assigned
Filed: December 9, 2003
For: SYSTEMS AND METHODS RELATED TO
DEGRADATION OF UREMIC TOXINS

Examiner: Not Yet Assigned
Art Unit: Not Yet Assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 16 day of April, 2004.


Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ PTO Form 1449 with cited references
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500.

A check is not enclosed, as no fee is believed due. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825.

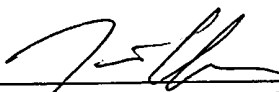


Serial No.: 10/731,877

Art Unit: Not Yet Assigned

A duplicate of this sheet is enclosed.

Respectfully submitted,
Jill A. O'Loughlin, et al., *Applicants*

By: 
Tanj Chen, Sc.D., Reg. No. 52,728
Helen C. Lockhart, Ph.D., Reg. No. 39,248
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Docket No. B0877.70025US00

Date: April 16, 2004

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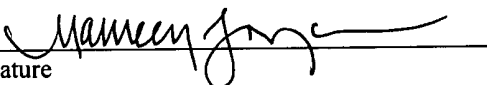
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Signature

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Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

PART II: Information Cited

Applicants hereby make of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, Applicants make no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

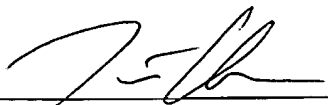
By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicants, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Jill A. O'Loughlin, et al., *Applicants*

By: 
Tani Chen, Sc.D., Reg. No. 52,728
Helen C. Lockhart, Ph.D., Reg. No. 39,248
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Docket No. B0877.70025US00

Date: April 16, 2004

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APR 19 2004

FORM PTO 9/A and B (Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 10/731,877

ATTY. DOCKET NO.: B0877.70025US00

FILING DATE: December 9, 2003

CONFIRMATION NO.: Not Yet Assigned

APPLICANT: Jill A. O'Loughlin, et al.

GROUP ART UNIT: Not Yet Assigned

EXAMINER: Not Yet Assigned

Sheet 1 of 2

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	1.	4,022,833		Diana et al.	05-10-1977
	2.	6,217,859	B1	Chang et al.	04-17-2001

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	3.	DAVANKOV, VADIM, et al., "Polymeric adsorbent for removing toxic proteins from blood of patients with kidney failure," <u>Journal of Chromatography B</u> , 739 (2000) 73-80.		
	4.	FRIEDMAN, ELI A., M.D., "Can Bacteria Be Trained to Do the Kidney's Work?" http://www.thedoctorwillseeyounow.com/articles/emerging_treatments/kidneyre... 2003-10-15, pp. 1-4.		
	5.	GARDNER, D. L., et al., "An Orally Administered Microcapsule System for Treating Chronic Renal Failure Patients," <u>Applied Biochemistry and Biotechnology</u> , Vol. 10, 1984, pp. 27-40, Received November 1983; Accepted December 1983.		
	6.	MALCHESKY, PAUL S., M.S., et al., "Biological reactors as artificial organs: Concept and preliminary in vitro study," <u>Cleveland Clinic Quarterly</u> , 42: 267-271, Vol. 42, No. 3, Fall 1975.		
	7.	O'LOUGHLIN, J. A., et al., "Microencapsulated Enzymes for Enteral Removal of Uremic Toxins," <u>Blood Purification</u> , 2003; 21: 350-367, 21st Annual Meeting of the International Society of Blood Purification (ISBP), Uncasville, CT, September 2003, (Abstract).		
	8.	O'LOUGHLIN, J. A., et al., "Degradation of Uremic Toxins With Free and Encapsulated Enzymes," Presented at the meeting of the American Society of Artificial and Internal Organs (ASAIO), Washington, DC, June 2003, (Abstract).		
	9.	O'LOUGHLIN, J. A., et al., "Kinetics of Urea Degradation By Genetically Modified E. Coli," Presented at the meeting of the American Society of Artificial and Internal Organs (ASAIO), New York, NY, June 2002, p. 194, (Abstract).		
	10.	O'LOUGHLIN, J. A., et al., "Encapsulation of Mammalian And Bacterial Cells," Presented at the meeting for the Materials Research Society (MRS), Boston, MA, November 2001, p. 640, (Abstract).		
	11.	O'LOUGHLIN, J. A., et al., "Release Of Albumin From Alginate Microspheres," Presented at the meeting for the Proceedings of the Controlled Release Society, San Diego, CA, June 2001, # 6042, (Abstract).		
	12.	O'LOUGHLIN, J. A., et al., "Degradation of Uremic Toxins With Free and Encapsulated Enzymes," Presented at the meeting of the Controlled Release Society, Glasgow, Scotland, June 2003, (Abstract).		
	13.	PRAKASH, S., et al., "Microencapsulated genetically engineered live E. Coli DH5 cells administered orally to maintain normal plasma urea level in uremic rats," <u>Nature Medicine</u> , Volume 2, Number 8, August 1996, pp. 883-887.		

—	14.	PRAKASH, S., et al., “ <i>In vitro</i> and <i>in vivo</i> uric acid lowering by artificial cells containing microencapsulated genetically engineered <i>E. Coli</i> DH5 cells,” <u>The International Journal of Artificial Organs</u> , Vol. 23, No. 7, 1000, pp. 429-435.		
.	15.	RONCO, CLAUDIO, et al., “First Clinical Experience with an Adjunctive Hemoperfusion Device Designed Specifically to Remove β_2 -Microglobulin in Hemodialysis,” <u>Blood Purification</u> , 2001; 19: 260-263.		
.	16.	SETALA, K., et al., “Bacterial enzymes in uremia management,” <u>Kidney International</u> , Vol. 13, Suppl. 8 (1978), pp. S-194 – S-202.		
	17.	SETALA, K., et al., “Treating uremia with soil bacterial enzymes: further developments*,” <u>Clinical Nephrology</u> , Vo. 11, No. 3 – 1979 (pp. 156-166).		
	18.	WINCHESTER, JAMES F., et al., “Sorbent Augmented Dialysis: Minor Addition or Major Advance in Therapy?” <u>Blood Purification</u> , 2001; 19: 255-259.		
‘	19.	WOLFE, E. A., et al., “Orally ingested microencapsulated urease and an adsorbent, zirconium phosphate, to remove urea in kidney failure,” <u>The International Journal Of Artificial Organs</u> , Vol. 10, No. 4, 1987, pp. 269-274.		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.